REMARKS

I. Introduction

Applicants have amended the priority claim to correct typographical errors as suggested by the Examiner and to update the status of the parent application. In addition, the title has been amended to more accurately reflect the claimed subject matter. Applicants have also corrected a typographical error with respect to the spelling of "Malhotra *et al.*" and point out that the correct spelling was provided on the PTO-1449 form filed by Applicants on February 14, 2002. Finally, claim 9 has been deleted and claim 10 has been amended to more clearly define the claimed subject matter.

II. The objection to the specification may be withdrawn.

The Examiner objected to the specification for the recitation of an improper relationship between PCT/JP95/02035 and U.S. Patent No. 6,110,708. The Examiner also objected to the title of the invention as filed for assertedly lacking consistency with the claimed subject matter. As indicated in the instant amendment, Applicants submit that the aforementioned formalities have been corrected. Accordingly, the Examiner's objection to the specification may be withdrawn.

III. The rejection of claims 9 and 10 under 35 U.S.C. § 112, first paragraph, may be withdrawn.

The Examiner rejected claims 9 and 10 for assertedly failing to comply with the enablement requirement. Specifically, the Examiner asserted that the breadth of the claims is excessive with regard to Applicants claiming all MBPs which have either budding inhibition or anti-influenza A activity. Moreover, the Examiner asserted that Applicants have only provided guidance and working examples of the effect of MBPs in Table 5 and 6 and figure 13 on specific activities of the Influenza A virus.

In response, Applicants first point out to the Examiner that claim 9, directed to a MBP having budding inhibition activity, has been canceled. Accordingly, the Examiner's assertion that Applicants have failed to disclose "...working examples of any MBP which has budding inhibition" is moot.

Examiner admits that Applicants have "...demonstrated that a small set of MBPs can have an activity on Influenza A activity." Nevertheless, the Examiner asserts that "most of the Examples provided in the specification demonstrate the effects of conglutinin, not MBPs." In response, Applicants point the Examiner to Examples 7 and 8 of the specification as filed. Specifically, Example 7, although demonstrating the effect of conglutinin on viral growth, sets out the procedure for assaying viral growth inhibition activities of collectins generally. Indeed, Example 8 which demonstrates the neutralization activities of various collectins against Influenza A viruses refers to the method set out in Example 7:

> Physiological activities against Influenza A viruses were evaluated in accordance with the evaluation method on Hemagglutination Inhibition (HI) Activities according to Example 5, the evaluation method on Neutralization Activities according to Example 6, the evaluation on Hemagglutination (HA) Activities by Western blotting, and the present method referred to in Example 7. (See page 15, lines 19-23, of the specification)

Thus, Example 8 illustrates the methodologies set forth in the previous Examples, including Example 7. As suggested in Example 8, the results set out in Tables 4 and 6, as well as figure 13, indicate that native hMBP inhibits viral growth (i.e., inhibits spread of infection).

The Examiner also rejected claims 9-10 for assertedly failing to disclose a representative number of species to describe the purported genus recited in the claims. In response, Applicants would like to clarify for the Examiner the meaning of the term "MBP." As used in the instant invention, the term "MBP" is not a generic name encompassing all mannose-binding proteins (i.e., MBP, SP-D, SP-A, and conglutinin). Rather, the term "hMBP" recited in claim 10 refers to the natural, human, full-length MBP which is comprised of a collagen-like region, a neck region, a carbohydrate recognition domain (CRD), and a N-terminal region carrying cysteine.

For the foregoing reasons, Applicants submit that the rejection of claims 9-10 under 35 U.S.C. § 112, first paragraph, has been overcome and should be withdrawn.

IV. The rejection of claims 10 and under 35 U.S.C. § 112, second paragraph, may be withdrawn.

The Examiner rejected claim 10 under 35 U.S.C. § 112, second paragraph, for assertedly failing to particularly point out and distinctly claim he subject matter which the Applicant regards as the invention. Specifically, the Examiner asserts that the metes and bounds of the phrase "an N-terminal region containing cysteine, a collagen-like region, a neck region and an carbohydrate recognition domain" is unknown. The Examiner further asserts that the preamble of the claim recites a purified mannan-binding protein while the remainder of the claim recites "calcium-dependent lectin."

In response, Applicants have amended claim 10 to recite the phrase " the hMBP comprises a collagen-like region, a neck region, a carbohydrate recognition domain (CRD) and an N-terminal region carrying cysteine." One of ordinary skill in the art would readily recognize that, provided such teachings and the teachings at, for example, page 1, lines 12-15, of the specification as originally filed, MBP is comprised of a basic unit of four unique regions. In fact, Malhotra *et al.*, cited in the specification at page 1, lines 14-15, teach that the aforementioned collagen-like region and ability to bind carbohydrates are general characteristics of collectins (See, e.g., page 1444, bottom of left column and bridging right column). Moreover, applicants have amended claim 10 to replace the recitation of the term "calcium-dependent lectin" with the term "hMBP." Accordingly, Applicants submit that the rejection of claim 10 under 35 U.S.C. § 112, second paragraph should be withdrawn.

V. The rejection of claims 9-10 and under 35 U.S.C. § 102(b), may be withdrawn.

The Examiner rejected claims 9-10 under 35 U.S.C. § 102(b) as being anticipated by Wakamiya *et al.* The Examiner further rejected claims 9-10 under 35 U.S.C. § 102(b) as being anticipated by Hartley *et al.* Applicants first point out that claim 9 has been canceled in the instant amendment.

The Examiner asserts that Wakamiya *et al.* teach a MBP having anti-Influenza A activity which would inherently have the ability to inhibit viral budding. In response, Applicants point out that Wakamiya *et al.* teach the anti-viral activity by bovine MBP and conglutinin, not hMBP. Claim 10 is directed to a purified and isolated Human Mannan-

binding protein (hMBP) possessing anti-Influenza virus activity. As discussed above, hMBP is a separate protein from bovine conglutinin.

The Examiner also asserts that Hartley *et al.* teach a purified MBP having anti-Influenza a activity which would inherently have the ability to inhibit viral budding. In response, Applicants point out that Hartley *et al.* teach that the "β-inhibitor in bovine serum is conglutinin" (See, e.g., title of Hartley *et al.*). Further, Hartley *et al.* teach that bovine mannan-binding factor was eluted and isolated as a fraction by applying bovine serum to a Sepharose 4B-CL column coupled with mannan from *S. cerevisiae*. (See page 4359, left column) As the authors admit, since it was unknown as to what substances were contained in such fractions, they denoted it simply as "mannan-binding factor." Even further, there is no recitation in Hartley *et al.* of hMBP, let alone the anti-Influenza activity of hMBP.

For the foregoing reasons, Applicants submit that the rejection of claims 9-10 under 35 U.S.C. § 102, has been overcome and should be withdrawn.

CONCLUSION

In view of the amendments and remarks made herein, Applicants submit that claim 10 is in condition for allowance and request notification of the same.

Dated: February 17, 2004

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